

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Natalie C. TWINE et al. Examiner: Channing Mahatan

Serial No. 10/717,597 Group Art Unit: 1631

Filed: November 21, 2003

For: METHODS FOR DIAGNOSING RCC AND OTHER SOLID TUMORS

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

The documents are being submitted within three (3) months of the filing of this application or entry into the national stage of this application, or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

It is requested that the accompanying PTO-1449 be considered and made of record in the above-identified application. To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initial a copy of this form be returned to the undersigned.

Application No. 10/717,597 Docket No. 031896-012000

The Commissioner is hereby authorized to charge any fees connected with this filing which may be required now, or credit any overpayment to Deposit Account No. 19-2380.

Respectfully submitted,

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Date: February 1, 2005

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Approved for use through 10/31/2002. OMB 0651-0031

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	Application Number	10/717,597
TRANSMITTAL FORM	Filing Date	November 21, 2003
(to be used for all correspondence after initial filing	) First Named Inventor	Natalie C. TWINE, et al.
	Group Art Unit	N/A
	Examiner Name	N/A
Total Number of Pages in This Submission	Attorney Docket Number	031896-012000 (AM 101080)

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ENCLOSURES (check all that apply)						
Fee Transmittal Fee Attached Amendment Affidavits/dd Extension of Tin Express Abandon Information Disc Certified Copy of Document(s) Response to Mis	d eclaration(s) ne Request nment Request closure Statement of Priority sing Parts/	Cor an a   Drawing     Declara     Licensin     Petition     Petition     Applica     Power of Change     Termina     Request	tion and Power of Attorney ag-related Papers  to Convert to a Provisional tion f Attorney, Revocation of Correspondence Address Il Disclaimer for Refund		After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Application Data Sheet Other Enclosure(s):	
Response to	Missing Parts R 1.52 or 1.53	CD, Number of CD(s)  Remarks  The Commissioner is hereby authorized to charge any additional fees required or credit any overpayments to Deposit Account No. 19-2380 (740819-383) for the above identified docket number.				
	SIGNATUI	RE OF APPL	ICANT, ATTORNEY, O	R AC	GENT	
Firm or Individual name  Raymond Van Dyke, Reg. No.34,746 Nixon Peabody LLP 409 9 <sup>th</sup> Street, N.W. Suite 900 Washington, D.C. 20004-2128						
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PE TOWN

Complete if Known Substitute for form 1449A/PTO 10/717,597 Application Number INFORMATION DISCLOSURE November 21, 2003 Filing Date STATEMENT BY APPLICANT TWINE et al First Named Inventor (use as many sheets as necessary) Not yet assigned Art Unit Not yet assigned Examiner Name Sheet of Attorney Docket Number 031896-012000 (AM 101080)

			FOREIGN PATENT	DOCUMENTS		
Examiner Initials*	Cite No. 1	Fereign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ°
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Co				
		WO00/040749	07-13-00	Chin		
		WO02/040000	05-23-02	Dukart et al.		
		WO01/081916	11-01-01	Ma et al.		
		WO03/032813	04-24-03	Gerritsen et al.		
		WO04/072265	08-26-04	Donner et al.		
		WO04/048933	06-10-04	Stover et al.		

Examiner Signature		Date Considered			
		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the No. item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.				
		BURCZYNSKI et al., "Pharmacogenomic expression profiling of renal cell carcinoma in a phase II trial of CCI-779: identification of surrogate markers of disease and predictors of outcome in the compartment of peripheral blood", European Journal of Cancer, Pergamon Press, Oxford, GB, vol. 38, November 11, 2002, page S51			
	SCHULZE-KOOPS, H. et al., "Persistent reduction in IL-6 mRNA in peripheral blood mononuclear cells of patients with rheumatoid arthritis after treatment with a monoclonal antibody to CD54 (ICAM-1)", Clinical and Experimental Immunology, vol. 106, no. 2, November 1996, pages 190-196				
		DIPAOLA, R.S., et al., "Phase I clinical and pharmacologic study of 13-cis-retinoic acid, interferon alfa, and paclitaxel in patients with prostate cancer and other advanced malignancies," <i>Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology</i> , Vol. 17, no. 7, July 1999, pages 2213-2218			
		"Product Catalogue", January 2001, Affymetrix, pages 1			
		LICHTENFELS, R. et al., "Identification of metabolic enzymes in renal cell carcinoma utilizing PROTEOMEX analyses", <i>Biochimica et Biophysica Acta</i> , Vol. 1646, No. 1-2, March 21, 2003, pages 21-31			
		SU, ANDREW I., et al., "Large-scale analysis of the human and mouse transcriptomes," Proceedings of the National Academy of Sciences of the United States of America, Vol. 99, No. 7, April 2, 2002, pages 4465-4470			
		DATABASE SOURCE Online!, <a href="http://genome-www5.stanford.edu/cgi-bin/source/expressionSearch?option=cluster&amp;criteria=Hs">http://genome-www5.stanford.edu/cgi-bin/source/expressionSearch?option=cluster&amp;criteria=Hs</a> . 171501&organism=Hs abstract			

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Of

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Complete if Known				
Application Number	10/717,597			
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First Named Inventor	TWINE et al			
Art Unit	Not yet assigned			
Examiner Name	Not yet assigned			
Attorney Docket Number	031896-012000 (AM 101080)			

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
		ELIT, LAURIE, "CCI-779 Wyeth," Current Opinion in Investigational Drugs (London, England: 2000), Vol. 3, No. 8, August 2002, pages 1249-1253			
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		RININGER, J., et al., "Differential gene expression technologies for identifying surrogate markers of drug efficacy and toxicity", <i>Drug Discovery Today United Kingdom</i> , Vol. 5, No. 12, December 1, 2000, pages 560-568			
		PCT International Search Report; PCT/US2004/006601; November 19, 2004; 4 pages			
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